JUL 3 2002

K021827

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000
Contact Person: Mike Flis
Date Prepared:

2) Device name

Proprietary name: Accu-Chek Active System
Classification name: SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER
(21 C.F.R. § 862.1345)(75NBW)

3) Predicate device

We claim substantial equivalence to the current legally marketed Accu-Chek Active System (K012324 & K021448)

4) Device Description

Instrument Operating Principle -- photometry
Reagent Test Principle -- glucose dehydrogenase

5) Intended use

The Accu-Chek Active system is designed to quantitatively measure the concentration of glucose in capillary whole blood. The device is indicated for professional use and over-the-counter sale. The Accu-Chek Active system is indicated for use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf and palm.

Continued on next page

6) Similarities The proposed modification is relatively modest in scope. All of the following are claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Intended use	The Accu-Chek Active systems is designed to quantitatively measure the concentration of glucose in whole blood. The test device is indicated for professional use and over-the-counter sale. This device is not suitable for testing neonate samples.
Test principle	Glucose dehydrogenase chemical reaction. The instrument measures the extent of color change (photometric) caused by the presence of glucose in the sample. The amount of color change is related to the glucose concentration in the blood sample.
Warnings and precautions	For *in vitro* diagnostic use only.
Under-dosed test strip detection method	Yes. Includes a third LCD intended solely to detect whether the test pad is sufficiently covered by the blood sample. This design more effectively identifies under-dosed test strips.
Dosing test strips outside of meter	Possible
AST precautionary instructions	AST is not recommended: – during periods of rapid decreases or increases in blood glucose levels; – for people with a history of recurrent hypoglyecmia, who suspect that their blood glucose is extremely low, or who are unaware of hypoglycemic events. Studies show that AST results immediately before a meal and near bedtime are more similar to fingertip results.

7) Differences

Feature	Accu-Chek Active System (modified)	Accu-Chek Active System (predicate)
Self-testing sample collection sites	Finger, forearm, calf, thigh, upper arm, and palm	Finger, forearm, calf, thigh, and upper arm

Continued on next page

510(k) Summary, Continued

8) Data demonstrating substantial equivalence

The results of a study conducted at our manufacturing facility demonstrated consistent quality performance of this product. This study demonstrated good correlation (r> 0.90) between AST results and finger results under steady state conditions. With these data it is proved that the system accuracy with AST blood from calf, thigh and upper arm is unchanged from forearm.

AST Sample versus Finger (Same Accu-Chek Active Meter)

AST Location	Palm (near thumb)	Palm (near small finger)
N	65	65
Range (mg/dL)	31-371	31-371
Slope	1.031	1.019
Slope 95% CI	(0.994, 1.067)	(0.978, 1.059)
Intercept	-0.5	1.7
Intercept 95% CI	(-6.7, 5.6)	(-5.1, 8.5)
Correlation	0.990	0.988
Std Error	11.0	12.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 2002

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k021827
Trade/Device Name: Accu-Chek Active System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; LFR
Dated: June 3, 2002
Received: June 4, 2002

Dear Mr. Flis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K021827
Device Name: Accu-Chek Active Test System

Indications for Use:

The Accu-Chek Active system is designed to quantitatively measure the concentration of glucose in capillary whole blood. The device is indicated for professional use and over-the-counter sale.

The Accu-Chek Active system is indicated for use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf and palm.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021827

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)